REMARKS

The Applicants have amended independent claims 1 and 41. In particular, claims 1 and 41 have been amended by recitation of the phrase "in said graft" in the body of the claim. These recitations have the effect of incorporating the "graft" of preamble into the body of the claims by reference back to it. Accordingly, these amendments are merely stylistic and do not add new matter. Claims 1 and 41 have been amended to recite that the "bone tunnel" is "substantially cylindrical." Support for "substantially cylindrical" is found in bone tunnels 462 and 466, described on page 6, and depicted in FIG. 4 of the specification. In addition, claim 41 has been amended to more completely parallel claim 1 by recitation of the ultimate phrase "each of said first bone block and said second bone block has a machined groove along its length for accommodating an interference screw for fixing said bone block in said bone tunnel." Support for the "machined groove" in both bone blocks is found in claim 1 and in the specification at page 2, last 2 lines (". . . .wherein at least one of said one or more bone blocks has a groove for accommodating a fixation screw."); at page 4, last 3 lines (The radius cuts 115, 125 aid in the attachment of the graft to the recipient because they provide a groove to position a fixation screw . . . ."); and at page 6, lines 8-9 ("further shaped by machining through conventional methods known in the art."). Support for an "interference screw" is found in the specification at page 5, lines 6-7 ("In a preferred embodiment, fixation is accomplished by interference screws and/or self tapping screws.").

For all these reasons, the amendments to the claims do not add new matter.

Summary of the Bases for Rejection

Claims 1, 2, 4, 8, 9 and 31-44 are rejected under 35 U.S.C. §103(a) for being allegedly unpatentable over U.S. Pat. 5,067,962 ("Campbell") in view U.S. Patent No. 5,562,669 ("McGuire").

I. 35 U.S.C. §103(a) Campbell in view of McGuire

Claims 1, 2, 4, 8, 9, and 31-44 are rejected under 35 U.S.C. §103(a) for being allegedly unpatentable over U.S. Pat 5,067,962 ("Campbell") in view U.S. Patent

No. 5,562,669 ("McGuire"). Claim 1 is directed to "A xenogenic bone-tendon-bone graft **suitable for fixation in a bone tunnel** during orthopedic surgery on a human, **comprising** a first bone block, a second bone block, and a tendon interconnecting said first bone block to said second bone block by a naturally occurring tendon-to-bone attachment, wherein each of said first bone block and said second bone block of said graft is **dowel shaped and sized for pulling through said bone tunnel** and each of said first bone block and said second bone block has a machined groove along its length for accommodating an interference screw for fixing said bone block in said bone tunnel." [Emphasis added in bold.] Independent claim 41, which parallels claim 1 and uses the transition word "consisting essentially of" instead of the open term "comprising," recites as follows: "A xenogenic bone-tendon-bone graft **suitable for fixation in a bone tunnel** during orthopedic surgery on a human, **consisting essentially of** a first bone block, a second bone block, and a tendon interconnecting said first bone block to said second bone block by a naturally occurring tendon-to-bone attachment, wherein each of said first bone block and said second bone block is **dowel shaped and sized for pulling through said bone tunnel** and each of said first bone block and said second bone block has a machined groove along its length for accommodating an interference screw for fixing said bone block in said bone tunnel."

A. Construing Applicants' Claims

As discussed above, claim 1 uses the transition word "comprising, whereas claim 41, which parallels claim 1, uses the transition phrase "consisting essentially of." According to the Patent Office, "The Campbell reference clearly discloses the specified structural elements that the Applicants' representative is claiming and **those structures [of Campbell] do not materially affect the basic and novel characteristics of the claimed invention**." [Official Action at age 2.] Applicants respectfully disagree.

Each of claims 1 and 41 recites that the claimed xenogeneic bone-tendon-bone graft is "**suitable for fixation in a substantially cylindrical bone tunnel** during orthopedic surgery." The word "tunnel" is understood in the art as being a passageway from one end to another (as shown in Applicants' FIG. 4) and being of substantially uniform cross sectional width (e.g., FIG. 4 the Holland tunnel, the Eisenhower tunnel

through the mountain on I-70 in CO.). Consistent with this definition, Campbell, as one skilled in the art, describes bone tunnels wherein one has an entrance and an exit as shown in Applicants' FIG. 4:

> Attachment of a replacement ligament according to **existing techniques** may involve **forming tunnels** in the **femur and tibia (the host bones)**. The tunnels are formed so that each **extends through one of the host bones** from an **entrance** or proximal end of the tunnel at the natural ligament attachment site to an **exit** or distal end of the tunnel at an outer surface of the host bone.
>
> [Campbell at col. 1 lines 19-26; emphasis added in bold.]

Campbell then discloses that "[e]ach end of the replacement ligament is **passed through** one of the tunnels, from the proximal end to the distal end where it is anchored to the outer surface of the host bone by such means as stapling." [Campbell at col. 1, lines 27-30; emphasis added in bold.] Likewise, U.S. Pat. 5,562,669 (McGuire), which is cited as prior art, teaches in its FIG. 1 a bone tunnel 16 that passes through the tibia 12 as disclosed in FIG. 4 of the Applicants' specification. Thus, those skilled in the art understand what is meant by the phrase "**suitable for fixation in a substantially cylindrical bone tunnel** during orthopedic surgery."

In contrast to Applicants' claimed BTB for use in a bone tunnel, Campbell shows a BTB having opposing frustoconical shaped bone plugs shaped for **snuggly fitting** (seating) into corresponding frustoconically shaped dead ends cut into opposing faces of a knee joint. Not only are the snuggly fitting frustoconical plugs of Campbell not shaped for **passing through** or fixation "in a substantially cylindrical bone tunnel" as the Applicants claim, but Campbell **teaches away** from the use of bone tunnels by teaching their problems, including ligament fatigue, irritation, leakage, and infection:

> In addition, **formations** such as **bone spicules** can form at the entrance to each of the tunnels. These tend to **abrade the replacement ligament**, cause **fatigue** of the material, and break off particles which can cause **irritation**.
>
> Furthermore, the **tunnels provide access** to the host bone interior. As a result, **synovial fluid can migrate from the intra-articular region between host bones into the bone tunnels**. Thus, any

> activity in the intra-articular region, such as **infection**, can be easily **communicated** into the bone interior and result in **intra-osseous complications**.
>
> [Campbell at col. 1, lines 43-54; emphasis added in bold.]

Campbell's solution is a "new and improved **replacement ligament** and **attachment method** that overcomes these concerns." [Campbell at col. 1, lines 56-58.] Campbell's new and improved "**replacement ligament**" is flush mounted with the joint surface and has no grooves along its length which would cause the leakage of synovial fluid into the joint (i.e., the very problem that Campbell solves). Campbell's new and improved "**attachment method**" comprises **medially** inserting a pin through the patients' bone and the seated frustoconical bone block (i.e., outside the joint) which also prevents leakage of synovial fluid into the frustoconically shaped hole that receives the frustoconically shaped bone block. Accordingly, the frustoconically shaped bone plugs of Campbell's invention which must not have a groove, and Campbell's sealing (**by seating**) "attachment method," and the use of a medial driven bone pins **materially affect the basic and novel characteristics of Applicant's claimed invention** which requires **non-seating** bone plugs that are shaped and sized for sliding through a substantially cylindrical bone tunnel and that are grooved along their length to accommodate an interference screw for fixing the bone blocks in the substantially cylindrical bone tunnel.

Thus, the word "consisting essentially of," which is used in Applicant's claim 41, limits claim 41 to grafts that are shaped and grooved to be "**suitable for [sliding and] fixation in a substantially cylindrical bone tunnel** during orthopedic surgery," and **would exclude** those sealing and seating shapes (frustoconical and no grooves) and features (through holes for fixation by a medially inserted pins) found in the graft of Campbell that are expressly stated to be suited for "a new and improved . . . attachment method that overcomes these [bone tunnel] concerns."

B. The Combination of Campbell and McGuire Fails to Make a Prima Facie Case of Obviousness

According to the Patent Office, Campbell discloses a "bone tendon bone graft comprising two bone plugs (23 & 24) connected by a tendon (16)" and that the "bone

plugs are shaped in a **dowel** (see Fig. 3), **comprise exterior, interior surfaces, having a groove** (25 & 26)." [Official Action at page 3; emphasis added in bold.] The Applicants respectfully disagree. According to FIGs 3 and 4 of Campbell, and Campbell's own description, each of elements 25 and 26 of Campbell is a "hole." [Campbell at col. 4, lines 35 ("hole 25") and 40 ("hole 26").] A groove in a surface has a bottom on the surface (like a groove in a phonograph record), a hole (such as the **through holes** of Campbell) do not have a bottom on the surface. They are bottomless. Hence, one skilled in the art, including Campbell, recognized that 25 and 26 of Campbell's figures are a "hole" and not a "groove." Moreover, the Patent Office later admits that "**Campbell et al does not disclose a groove along its length**." [Official Action at page 3.] Next, the Patent Office also contends that "the bone plugs [of Campbell] are made of xenograft material (see abstract)." [Official Action at page 3.] On this latter point, the Applicants agree.

To make up for the admitted deficiency in Campbell, the Patent Office cites to McGuire. According to the Patent Office, McGuire "discloses first and second bones having a **plurality of longitudinal grooves** and connected to each other by a graft ligament." [Official Action at page 3; emphasis added in bold.] However, in the **graft** of McGuire, the two longitudinal grooves on each of the two bone blocks perform a very different function (*i.e.*, they provide a notch for aligning and holding the tendon) and they are not free for engaging an interference screw. Rather, in the "graft" of McGuire, the **grooves** are **occupied** by tendons 20 and 21 that are sutured thereto as shown in the assembled graft of FIG. 5 and the cross sectional view of the implanted graft in FIG. 6:

> The semitendinosus tendon 20 and/or gracilis 21 is extended between both of the bone plugs 25. The **tendons** are **seated inside the two substantially parallel grooves 50** and about an end **of each bone plug**. The tendons are preferably sutured to themselves to form a double loop as shown in FIG. 5. **Sutures** are also used **through the suture holes to attach the tendon to each of the bone plugs**.
>
> [McGuire at col. 5, lines 1-7; emphasis added in bold.]

Thus, McGuire teaches that in the "graft" (as opposed to the free bone block component) the "grooves" are filled with "seated" tendon, and not freely available for engaging an interference screw. Further, in FIG. 6 of McGuire, McGuire discloses a

"cross sectional view of FIG. 1 taken along lines 6-6." [McGuire at col. 2, lines 27-28.] Figure 6 shows the cross-sectional view of the graft positioned in the bone tunnel 16 wherein the bone tunnel has a pair of grooves (like Mickey Mouse ears) cut into the side to accommodate the thickness of the tendon (20 and 21) which overflows from the grooves on the bone blocks to the grooves on the tunnel. In addition in FIG. 6, the **bone tunnel** (and **not the bone block**) is shown as having an additional groove at the top of the tunnel 16 to accommodate the interference screw 82. More importantly, McGuire teaches that in the graft, the bone block grooves accommodating the tendon cannot also be used for the interference screw because the threads of the screw would "**cut or tear the tendon**":

> **In affixing the composite graft 80 within a bone tunnel, contact between a screw 82 and the tendon should be avoided so as not to cut or tear the tendon.** To better **insure** that the screw is out of contact with the tendon, an interference screw should be driven along the bone portion of the graft between the graft and the bone tunnel wall. A trefoil rasp 90 of the present invention is recommended for use prior to fixation of the graft. **As shown in FIGS. 3a and 3b, the trefoil rasp 90 has three longitudinal lobes for use in cutting three channels into each of the bone tunnels.** Reciprocating movement of the trefoil rasp 90 in and out of the bone tunnels 16 serves to file away the tunnel walls to form the desired channels. Two of the longitudinal lobes 92 are 180.degree. apart on the rasp. These longitudinal lobes 92 are used to form channels for accommodating **the semitendinosus tendons 20 and gracilis 21 seated in the parallel grooves of the bone graft**. When the gracilis 21 is attached along and on top of the semitendinosus tendon 20, the channels are required to provide room for the graft to fit within the tunnel.
>
> [McGuire at col. 5, lines 17-35; emphasis added in bold.]

Thus, when McGuire is considered for all that it discloses, it fails to disclose a graft having a bone block having a free **groove** along its length for "for accommodating an interference screw for fixing said bone block in said bone tunnel." Rather, in the "**graft**" of McGuire (which is the relevant device for comparison to the Applicants' claimed graft), the grooves are **filled** and **overflowing** with tendon (FIG. 6), and McGuire teaches that "**contact between a screw 82 and the tendon should be avoided so as not to cut or tear the**

tendon." As shown in FIG. 6 of McGuire, McGuire's solution was to put a groove in the tunnel 90° away from the tendons that fill the grooves in the bone blocks.

Accordingly, even when McGuire and Campbell are combined, the combination does not teach or suggest the Applicants' solution to the problem of providing a BTB having the Applicants' claimed combination of structure and mode for facilitating fixation in a bone tunnel. For this reason, the combination of Campbell and McGuire would fail to make a prima facie case of obviousness against claims 1 and 41 and their dependents (claims 2, 4, 8-9, 31-40, and 42-44).

In addition, the **"divergent" paths** chosen by both Campbell (eliminate bone tunnels which leak with a seated bone blocks that seals) and McGuire (grooved bone tunnels (and not bone block) to accommodate a screw to fix a slideable bone block wrapped on 2 sides by tendon), would lead one **"in a direction divergent from the path taken by the applicant"** and thus, **teach away** from the Applicants' invention. *See Monarch Knitting v. Sulzer*, 45 USPQ2d 1977, 1984 (Fed. Cir. 1998) ("A prior art reference may be considered to teach away when 'a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or **would be led in a direction divergent from the path taken by the applicant**.")

Regarding claim 9, the Patent Office states that "the threads can be done by the insertion of the interference screw." Regarding claim 31, the Patent Office states that McGuire discloses bone blocks capable of being "utilized bi-directionally" (see Figs. 1, 4a, and 4b). [Official Action at page 4.] Regarding claims 34 and 37, the Patent Office states that "at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the shape of the Campbell et al reference by having a cylindrical shape or square cross section because Application has not disclosed that the cylindrical shape provides an advantage, is used for a particular purpose, or solves a stated problem." The Patent Office also states that "[o]ne of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with taper shape of the Campbell et al reference because it will perform equally the same." [Official Action at page 3.] The Patent Office concludes that "[t]herefore, it would have been an obvious matter of design choice to modify [the] Campbell et al reference to obtain

the invention as specified in claim 34" [Official Action at page 3.] The Applicants respectfully disagree.

The Patent Office states that "[r]egarding claim 35, Campbell et al disclose the claimed invention except for a cylindrical dowel diameter of 9 through 12 mm." The Patent Office concludes that "[i]t would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the diameter of the Campbell et al reference with the optimum value of 9 through 12mm, since it has been held that finding an optimum value of a result effective variable involves only routine skill in the art." [Official Action at page 3.] The Applicants respectfully disagree.

A. Campbell does not disclose "a dowel"

As noted above, a factual basis underlying the Patent Office's conclusion of obviousness is that "the bone plugs [of Campbell] are shaped into a dowel (see Fig. 3)." [Official Action at page 2.] The Applicants respectfully disagree. By definition, a "dowel" is understood as meaning a peg or pin of **uniform** or substantially uniform circular diameter for fitting into hole of a corresponding diameter:

> **dowel**- a headless or barbed pin usually of **circular section** fitting into corresponding holes in abutting pieces to act as a temporary fastening or to keep them permanently in their proper relative position; *also* : a **round rod** or stick used especially **for cutting up into dowels**.
>
> [Exhibit A: Webster's Third New International Dictionary of the English Language Unabridged, Merriam-Webster Inc., Publishers, Springfield, MA, 2002 at page 681; emphasis added in bold.]
>
> * * *
>
> **dowel**- a pin, **usually round**, fitting into two adjacent pieces to prevent their slipping or to align them.
>
> [Exhibit B: Webster's Unabridged Dictionary of the English Language, Portland House, New York, 1983 at page 430; emphasis added in bold.]
>
> * * *

> **dowel-** a peg or pin of wood, metal, etc., usually fitted into corresponding holes in two pieces to fasten them together.
>
> [Exhibit C: Webster's New World Dictionary, Second College Edition, Ed, Prentiss Hall Press, 1986 at page 422; emphasis added in bold.]

Thus, each of these dictionary definitions defines a dowel as having a "circular" cross section or being a "pin". Moreover, each of these three dictionary definitions includes in the definition a picture, showing the "dowel" as being a pin of uniform or substantially uniform diameter so as to have side walls that are parallel or substantially parallel. Consistent with this, wooden "dowels" are commercially available in the hardware store in 3 foot lengths in a range of uniform "diameters" such as 1/8", 3/16", ¼", 3/8", ½", 5/8", ¾" etc.

In contrast to a "dowel," Campbell discloses a BTB having bone blocks that are "frustoconical" shaped, i.e., that are cone shaped with a blunt end.

> **frustum** – the part of a **conical** solid left after cutting off a top portion with a plane parallel to the base.
>
> [Exhibit B: Webster's Unabridged Dictionary of the English Language, Portland House, New York, 1983 at page 572; emphasis added in bold.]

Referring to the figure entitled "frustum of a cone" shown in Exhibit B at page 572, it can be seen that it is identical to the bone blocks of Campbell. Moreover, the term "frustoconical" is well-know in U.S. patent parlance for describing truncated cone-shapes, such as the truncated conical bone blocks of Campbell:

> The term "frustoconical surface" is defined by straight lines intersecting the edge of the annular base of the stopper and the apex so the resulting surface tapers evenly between the base and truncated tip surfaces.
>
> [Exhibit D: U.S. Pat. 4,826,029 (Skoglie), entitled "Stopper and method of use in association with wine barrels," at col. 1, lines 54-57.]

In Skoglie, the term "frustoconical surface" referred to the surface shape of stoppers that were placed in the filling hole in a wine barrel to seal the hole. See Exhibit D: Skoglie at page , FIGS. 3, 4 and 6, showing the frustoconical shaped stoppers. Thus, by definition, a "dowel" has side walls that are parallel or substantially parallel. In contrast, "frustoconical" shaped object has sidewalls that taper significantly such that the taper is visually apparent, as in the bone blocks of Campbell, the figure in the dictionary definition, or the stoppers of U.S. Pat. 4,826,029 (Skoglie). Accordingly, Campbell does not disclose "bone blocks shaped into a dowel." Campbell discloses "stopper" shaped implants that are stopped in a frustoconical surface (stopper shaped) hole. Thus, the Patent Office's conclusion of obviousness, which is based upon this erroneous finding of fact, is legally erroneous.

As an additional note added in proof of the difference between "plug" and "dowel" shapes, claims 1 and 38 recite that the claimed xenograft BTBs have bone blocks that are shaped like "dowels" to slide through a bone tunnel thereby excluding "plugs" such as the bone plugs of Campbell which are shaped to stop in a hole rather than slide through a bone tunnel.

For this reason claims 1, 2, 4, 8, 9, and 31-40 would not have been obvious under 35 U.S.C. §103(a) over U.S. Pat 5,067,962 ("Campbell") in view U.S. Patent No. 5,562,669 ("McGuire").

B. Campbell and McGuire take divergent approaches that teach away from one another

"A prior art reference may be considered to teach away when 'a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or **would be led in a direction divergent from the path taken by the applicant.**" *Monarch Knitting v. Sulzer*, 45 USPQ2d 1977, 1984 (Fed. Cir. 1998); emphasis added in bold. In the present case, the two references relied upon by the Patent Office take divergent approaches that teach away from one another. Moreover, there is no motivation or suggestion to take the groove from the implant of McGuire and add it to the implant of Campbell. Rather, Campbell teaches away from making such changes.

In particular, Campbell teaches away from using implants that require arthroscopy and endosteal bone tunnels. Campbell begins by teaching that "**success depends upon proper attachment to host bone**":

> Replacement ligaments can restore performance where native structures rupture beyond repair. But **success depends on proper attachment to the host bone**. Thus, the **manner** in which this is done and the related **details of prosthesis construction** are **important**.
>
> [Campbell at col. 1, lines 13-17; emphasis added in bold.]

By saying that the 'manner' of implantation and the '**details of prosthesis construction** are **important**,' Campbell was closing his prosthesis to changes in construction that would alter the inventive aspects or features invention.

One of the "**manners**" of implantation that Campbell specifically **taught away** from was the use of "**endosteal tunnels drilled in the bone**." Campbell **teaches away** from the use of "**endosteal tunnels drilled in the bone**" by pointing out several problems with that manner of implantation, and stating that as a result of these problems "it is desirable to have a **new** and improved **replacement ligament** and **attachment method** that overcomes these concerns."

> Consider, for example, an injured knee joint having a damaged anterior cruciate ligament. Attachment of a replacement ligament according to **existing techniques** may involve **forming tunnels** in the **femur and tibia (the host bones)**. The tunnels are formed so that each extends through one of the host bones from an entrance or proximal end of the tunnel at the natural ligament attachment site to an exit or distal end of the tunnel at an outer surface of the host bone.
>
> Each end of the replacement ligament is passed through one of the tunnels, from the proximal end to the distal end where it is anchored to the outer surface of the host bone by such means as stapling. This results in the replacement ligament spanning the intra-articular region between the natural attachment sites somewhat like a natural ligament, but it also results in certain problems that need to be overcome.
>
> For example, the **replacement ligament extends beyond the**

> **natural attachment sites** and **all the way through the tunnels** to the outer surfaces on the other side of each host bone. This **results in the replacement ligament being able to stretch over a greater length than a natural ligament** (from the outer surface of the femur to the outer surface of the tibia), and this **impairs performance**.
>
> In addition, **formations** such as **bone spicules** can form at the entrance to each of the tunnels. These tend to **abrade the replacement ligament**, cause **fatigue** of the material, and break off particles which can cause **irritation**.
>
> Furthermore, the **tunnels** provide access to the host bone interior. As a result, **synovial fluid can migrate from the intra-articular region between host bones into the bone tunnels**. Thus, any activity in the intra-articular region, such as **infection**, can be easily **communicated** into the bone interior and result in **intra-osseous complications**. Similarly, activity within the bone can be easily communicated to the intra-articular region.
>
> Consequently, it is desirable to have a **new** and improved **replacement ligament** and **attachment method** that overcomes these concerns.
>
> [Campbell at col. 1, lines 18-58; emphasis added in bold.]

Campbell teaches that **both** his "**replacement ligament**" (*i.e.*, BTB) and the "**attachment method**" are required to overcome these concerns. Therefore, Campbell **teaches away** from the use of endosteal tunnels and endosteal fixation.

The addition of grooves to each of the "bone plugs" of Campbell's replacement ligament (BTB) so that each "bone plug" could be fixed with an interference screw would defeat the expressly stated object of Campbell's invention. Campbell wants to maintain the natural attachment site of the ligament so he fixates the graft transversely by placing a "stainless steel pin" through each of the bone plugs and the patient's bone into which they are anchored. [Campbell at FIG. 4 and at col. 4, lines 26-40 discussing FIG. 4.] If one skilled in the art adheres to Campbell's "manner of attachment," which Campbell says is "important" [Campbell at col. 1, lines 16-17], that skilled person would never think of using any type of interference fixation. Placing an interference screw between the donor bone (even if grooved) and the recipient bone would displace the donor bone away from

the recipient bone at that point and would defeat the natural attachment which Campbell teaches as "important."

In addition, when the interference screw pushes the donor bone away from the recipient bone at the screw site, it would allow synovial fluid to enter the intraosseous space, thereby defeating Campbell's solution to a problem he recognized. The problem identified by Campbell is that the migration of synovial fluid "from the intra-articular region between host bones into the bone tunnels" means that "any activity in the intra-articular region, such as infection, can be easily communicated into the bone interior and result in the intra-osseous complications." Campbell's solution is a new and improved replacement ligament and attachment method with stopper shapes that overcomes the migration of synovial fluid in the intraosseous space, Campbell teaches away from the use of an interference screw. Therefore, there is no motivation to combine the invention of Campbell and the interference screws of McGuire. Therefore, it would not have been obvious to take the interference screw of McGuire and add it to the bone plugs of Campbell. Accordingly, a person skilled in the relevant art, would not have found the Applicants' xenograft BTB to have been obvious over Campbell in view of McGuire.

There is no motivation to combine Campbell with McGuire for yet another reason. Campbell used horizontal pins, which ran perpendicular to the direction of pull on the bone blocks, to prevent the tapered (stopper-shaped) bone blocks from falling out, or being pulled out of their tapered holes. There is no express suggestion in either Campbell or McGuire to take **the longitudinal groove of the McGuire reference** and add it to the side of the tapered xenograft bone-ligament-bone (aka Bone-Tendon-Bone) graft of Campbell. The reason that there is no express suggestion to do so is because any interference screw that pressed against the cork shaped graft of Campbell would have a downward component of force on the opposing wall that would literally pop the cork shaped graft out of the tapered hole.

To show this, Applicants have copied Fig. 2 of Campbell but deleted all of the lines pointing to the number of the various elements. For purposes of this analysis, Fig 2 is analogous to Fig. 4 of Campbell, because the shape of the tapered bone block is the same but there are less interfering lines. In the copied (but enlarged) Fig. 2 shown as **page 13 herein**, the Applicants have added the opposing force vectors (bolded arrows **R** and **X**)

to show the directly opposing forces that an interference screw would exert against the bone graft and the wall of the tapered hole in which it was inserted. Any interference screw that was wedged between hole wall **A** and tapered wall **B** of the bone graft would exert equal but opposing forces perpendicular to each of wall **A** and wall **B**. The force **R** against wall B then gets transferred by the bone graft against opposing wall **C**. However, using conventional vector analysis, the force of vector **R** exerted by the tapered bone graft against transferred to opposing hole wall **C** may be resolved into two components shown as **S** and **T**. The line of action of the first component **S** is perpendicular to hole wall C. However, the line of action of the second component **T** presses the tapered bone plug downward along (parallel to) hole wall **C** and out of the hole. Referring to enlarged Fig. 2, the force **R** that is exerted by an interference screw positioned between walls **A** and **B** has a **desired component** of force **S** **perpendicular** to hole wall **C** that is **equal** to the **undesired component** of force **T** that is pushing the tapered (cork shaped) implant down and out of the hole. Thus, as a matter of basic science, the forces exerted by an interference screw on a groove in the sidewall of the cork shaped implant of Campbell would literally pop the cork (or cork shaped implant) out of its hole (with or without pulling) and not provide a graft within the scope of the Applicants' claims, *i.e.*, "a xenograft bone-tendon- bone graft that would be **useful in orthopedic surgery . . . .**" This is yet another reason why Campbell chose the lateral hole and stainless steel pin combination. In Campbell, the tapered graft is retained in its position by lateral pins that resist all downward pressure, include downward pulling pressure during use, until such time as bone remodeling occurred. Any interference screw intended to retain the tapered implant of Campbell in its tapered hole would be non-operative for its purpose and would lack utility. For these reasons, adding the interference screw grooves of McGuire to the implant of Campbell would not give rise to an operative combination and certainly not the Applicants' claimed invention.

For all these reasons, the combination of Campbell in view of McGuire would not have made a *prima facie* case of obviousness against the claimed invention. *See In re Fine*, 5 USPQ2d 1596, 1599 (Fed. Cir. 1988) ("error to find obviousness where references 'diverge from and teach away from the invention at hand'"); *citing Gore v. Garlock*, 220 USPQ 303, 311 (Fed. Cir. 1983). Therefore, the allowance of claims 1, 2, 4,

8, 9 and 31-40 is respectfully requested. Narrower claims 41-44, which lack the structures of Campbell or Beck, alone or in combination, are free of the prior art.

SUMMARY

Claims 1, 2, 4, 8, 9 and 31-40 are rejected. Claims 41-44 have been added by amendment. In view of the arguments and evidence provided herein, all bases for rejecting claims 1, 2, 4, 8, 9 and 31-40 under 35 U.S.C. §103(a) for alleged obviousness have been rebutted. The allowance of claims 1, 2, 4, 8, 9 and 31-40 is respectfully requested. Narrower claims 41-44, which lack the structures of Campbell or Beck, alone or in combination, are free of the prior art.

Respectfully submitted,

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